Massachusetts Department of Public Health
Division of Epidemiology and Immunization
Vaccines for Children Program (VFC)

Guidelines for Compliance with Federal and State Vaccine Administration Requirement

Table of Contents

The following requirements regarding vaccine storage and handling, administration, documentation, reporting and information are in accordance with Section 317 of the Public Health Service Act, federal vaccine contract terms, the specifications of the National Childhood Vaccine Injury Act (NCVIA) of 1986 (Section 2125, of the Public Health Service Act), the Vaccines for Children Program (VFC) (Section 1928 of the Social Security Act) and the Massachusetts Department of Public Health (MDPH) Immunization Program.

A. Appropriate Use of State-supplied Vaccine

A-1. Providers must use state-supplied vaccine only for those children and adults determined eligible as defined in the most recent versions of the Childhood Vaccine Availability Table, the Adult Vaccine Availability Table and the Summary of the Advisory Committee on Immunization Practices Recommended Groups for Vaccination (available on the MDPH Immunization Program website by visiting http://www.mass.gov/dph/imm and selecting "Vaccine Management.")

A-2. VFC-only vaccines (see Childhood Vaccine Availability Table) must be offered only to VFC-eligible children. Children < 19 years of age in the following categories are eligible for VFC vaccine:

- Enrolled in Medicaid, or
- Without health insurance, or
- American Indian (Native American) or Alaska Native, or

- Underinsured children (coverage does not include vaccines or covers only selected vaccines) seen at federally qualified health centers (FQHC) and rural health centers (RHC).

Please note, children enrolled in sCHIP or the Children's Medical Security Plan (CMSP) are covered with state funds.

A-3. Providers must screen all children (birth through 18 years of age) at every immunization visit, as outlined in the Provider Enrollment Agreement, to determine eligibility to receive vaccine purchased with VFC funds. Providers must document the results of VFC screening at every immunization visit. Patient eligibility screening for VFC may be recorded electronically if all information requested in the *VFC Patient Eligibility Screening Form* is both recorded and retrievable in the event of a VFC site visit. . VFC Screening information must be retained in the electronic medical record or on file in the office for a minimum of 3 years after service to the patient has been completed.

A-4. Providers are expected to maintain an adequate inventory of vaccine for their non-VFC-eligible patients. State-supplied vaccine must not be used as a replacement system for a provider's privately purchased vaccine inventory. If the provider must borrow state-supplied vaccine to administer to privately insured children because private stock vaccine is unexpectedly unavailable, the provider must do the following:

- Assure that state-supplied vaccine supply is adequate to meet the needs of the provider's state-supplied eligible patients and that borrowing state-supplied vaccine will not prevent an eligible child from receiving a needed vaccination.
- Assure that borrowing occurs only when there is lack of private-stock vaccine due to unexpected circumstances such as a delayed vaccine shipment, vaccine spoiled in-transit to provider or new staff that calculated ordering time incorrectly.
- Complete the *MDPH VFC Vaccine Borrowing Report Form* whenever state-supplied vaccine that is only available to a state-supplied eligible child is administered to a non-state-supplied eligible child.
  - The provider must send a copy of the completed form with a copy of the vaccine replacement invoice to the Vaccine Unit. The original form should be kept on file as part of the VFC Program records and made accessible to MDPH staff during the VFC site visit.
- Send in the completed *MDPH VFC Vaccine Borrowing Report Form* to the Vaccine Unit with a copy of the invoice for the private stock vaccine used to replenish the borrowed state-supplied vaccine.

Borrowing of state-supplied vaccine should be rare and not a routine occurrence and should only occur to avoid a missed opportunity to provide a needed vaccine for a child who might otherwise not receive vaccine.

A-5. Fraud and Abuse: Improper use of VFC vaccine may constitute fraud and abuse and is punishable by law (Medicaid regulation: 42 CFR §455.2 and applicable state law). Please see section H (Provider Site Visits) for information about assessment and follow-up of fraud and abuse according to CDC guidelines.

Fraud is defined by the Centers for Disease Control and Prevention (CDC) as an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to him/herself or some other person. It includes any act that constitutes fraud under applicable federal or state law.

Abuse is defined by CDC as provider practices that are inconsistent with sound fiscal, business, or medical practices, and result in unnecessary cost to the Medicaid program, (and/or including actions that result in an unnecessary cost to the immunization program, a health insurance company, or a patient); or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care. It also includes recipient practices that result in unnecessary cost to the Medicaid program.

These fraud and abuse parameters apply to all state-supplied vaccines.

Fraud and abuse can include (but is not limited to):

- Selling or otherwise misdirecting VFC or other state-supplied vaccine.
- Billing a patient or third party for VFC or other state-supplied vaccine.
- Charging more than the established maximum regional charge for administration of a VFC vaccine to a federally vaccine-eligible child. (See section C-2)
- Not providing VFC-eligible children VFC vaccine because of parents' inability to pay for the administration fee.
- Not implementing provider enrollment requirements of the VFC program.
- Failing to screen patients for VFC eligibility.
- Failing to maintain VFC records and comply with other requirements of the VFC program.
- Failing to fully account for VFC or other state-supplied vaccine.
- Failing to properly receive, store or use VFC or state-supplied vaccine. The Massachusetts Department of Public Health (MDPH) may require providers to make restitution for any doses of federal or state-purchased vaccines that have been wasted due to the provider negligence/mismanagement. See section A-6 below for additional information about the restitution policy. Examples of provider negligence/mismanagement include (but are not limited too):
    - Failure to open vaccine shipments from McKesson or Merck immediately which results in damage to the vaccines.
    - Failure to rotate vaccine stock which results in expired vaccine.
    - Allowing vaccine to expire. You must transfer short-dated (soon to expire) vaccine to another practice 2-3 months prior to expiration. If unable to locate a practice, contact the Vaccine Unit for assistance at 617-983-6828.
    - Using VFC or state-supplied vaccines for unapproved groups.
    - Freezing vaccines meant to be refrigerated. (See section B-2 for more details)
    - Refrigerating vaccines meant to be frozen. (See section B-2 for more details)
    - Refrigerator or freezer left unplugged or electrical breaker switched off by provider staff, contractor or any other individual.
    - Refrigerator or freezer door left open or ajar by provider staff, contractor, or any other individual.
    - Vaccine that is left out of the refrigerator unit and becomes non-viable – always call the Vaccine Management Unit at 617-983-6828 to determine if vaccines can be identified as viable.
    - Any power outages in which the provider fails to act according to their vaccine storage back up plan.

- Ordering VFC vaccine in quantities or patterns that do not match provider profile or otherwise involve over-ordering of VFC or state-supplied vaccine doses.
- Wastage of VFC or other state-supplied vaccine.
- A refrigerator malfunction in a non-pharmaceutical grade unit that is being used as the primary vaccine storage unit for a pediatric provider. (See B-2)
- Any other handling and storage mistakes made by provider staff.

A-6. MDPH requires providers to make restitution for any doses of federal or state-purchased vaccines that have been lost due to the provider's failure to properly receive, store, or use vaccines (as outlined in section A-5) if:

a. it is the 1st incident and the total loss is over $10,000, or
b. it is the 2nd incident (or greater) regardless of total value, or
c. it is due to a failure to immediately open a vaccine shipment from McKesson or Merck resulting in damaged vaccine regardless of total value, or
d. it is due to a failure to store refrigerated vaccine in a refrigerator or failure to store frozen vaccine in a freezer.

MDPH will notify the provider in writing concerning the number of doses of each vaccine that must be replaced. Vaccine orders from the provider will not be processed by the Vaccine Management Unit until a copy of the invoice for the replacement vaccine has been received, reviewed and determined to be adequate by MDPH.

Please note that MDPH will only hold providers accountable in situations of provider negligence/mismanagement as outlined above and will not seek restitution for a vaccine loss that occurred due to a circumstance not in the provider's control (e.g. act of nature). Providers will be given due process to dispute cases of avoidable loss. Procedures for appealing a restitution decision will be included in the formal restitution notification given to practices. However, MDPH retains the right to make final determinations regarding vaccine restitution.

B. Vaccine Management

B-1. Providers must have written standard operating procedures (SOP) in place for proper vaccine management. The SOP for Vaccine Management must be reviewed and updated annually, or more frequently when there is a change in responsible staff and must include:

- Designation of a Primary Vaccine Coordinator and staff person who will act as their back up. Providers must notify the Vaccine Unit at 617-983-6828 within 10 days when a new Primary Vaccine Coordinator or their back up is designated.
- Proper storage and handling procedures.
- Vaccine receiving procedures.
- Vaccine relocation procedures in the event of a power or equipment failure.
- Vaccine ordering and inventory control procedures.
- Handling lost or expired vaccine procedures.
- Response procedures for when vaccine is stored out of temperature range.

- All staff who are responsible for administering vaccines and who may be required to transport vaccines in an emergency situation must acknowledge reading their practice's SOP for Vaccine Management by signing and dating the document.

A sample copy of MDPH's *SOP for Vaccine Management* can be found on the DPH website by going to: http://www.mass.gov/eohhs/docs/dph/cdc/immunization/vaccine-management-sop-sample.doc

B-2. Providers must agree to follow the manufacturer's specifications and the guidelines established by the MDPH Immunization Program for the storage and handling of vaccines.

Proper vaccine storage and handling includes:

- All vaccines, with the exception of varicella and MMRV vaccine, must be stored refrigerated between 2°C and 8°C (35°F and 46°F).
- Varicella and MMRV vaccine must be stored frozen between -50°C and -15°C (-58°F and 5°F). DO NOT store the diluent in the freezer; the diluent for these vaccines may be stored either in the refrigerator or at room temperature.
- MMR may be stored in the freezer to reduce the likelihood of a vaccine loss due to a refrigeration issue since MMR is much more temperature sensitive than other vaccines. Storing MMR in the freezer can also free up storage space in the refrigerator for other refrigerated vaccines. DO NOT store the diluent in the freezer; the diluent may be stored either in the refrigerator or at room temperature.
- Inventory must be clearly marked or identified so that providers can differentiate between state-supplied (which includes VFC vaccine) and privately purchased vaccine.
- **The use of any combination refrigerator/freezer unit that is outfitted with one external door for storage of any vaccines including temporary storage is strictly prohibited.**
- **PLEASE NOTE**: Effective January 1, 2016, MDPH now requires all pediatric practices (any site that administers at least some vaccines to those <19 years of age, excluding sites that only administer flu vaccine) to have pharmaceutical grade refrigerators for the primary vaccine storage unit in their facility. Stand-alone freezers that are not pharmaceutical grade will be acceptable. These units can vary in size from a compact, under the counter style to a large stand-alone unit. The size of the refrigerator should be able to accommodate your largest vaccine supply. The use of combination household refrigerator/freezer units with two doors but one compressor is not acceptable for your primary storage unit.

- Characteristics of pharmaceutical grade refrigerators include:
  - Internal overhead fans to disperse cold air throughout the unit, eliminating cold pockets of air
  - Adjustable wire shelves to allow better air flow
  - No storage bins, or shelves on door
  - Typically, pharmaceutical grade refrigerators have a narrow operating range (less than 2 Celsius degrees or 3 Fahrenheit degrees)
- "DO NOT DISCONNECT' signs must be placed on all refrigerator/freezer electrical outlets and circuit breakers.

- Refrigeration units must be plugged directly into a wall outlet. DO NOT plug refrigeration units into a power strip, surge protector, extension cord or a ground fault circuit (GFC) interrupter outlet.
- Food or beverages must **not** be stored in vaccine storage units.
- Vaccines should be stored centrally in the refrigerator and freezer, not in the doors, storage bins, or on the bottom of the unit or in front of the cold air duct and sufficiently away from the walls to allow for proper air circulation.
- There should be sufficient space between rows of vaccine boxes or bins and shelving units to allow proper air circulation.
- No vaccine should be stored on the top shelf of a household-style refrigerator. Place water bottles or cold packs on the top shelf.
- Using a NIST certified, calibrated, biosafe glycol-encased probe thermometer (product temperature thermometer), temperatures must be physically acknowledged at least twice daily for all vaccine storage units, preferably at the start of the work day and at the end of the work day.
  - It is also recommended for all practices and required for all pediatric practices (any site that administers at least some vaccines to those <19 years of age, excluding sites that only administer flu vaccine) to monitor the minimum and maximum temperatures daily.
  - Temperature reports or logs must be reviewed for completeness and out-of-range temperatures. Immediate action must be taken if temperatures are out of range. Report all vaccine storage and handling issues to the Vaccine Management Unit at 617-983-6828.
- MDPH requires the use of NIST certified calibrated digital data loggers for continuous 24-hour temperature monitoring on all primary vaccine storage units at all pediatric practices (any site that administers at least some vaccines to those <19 years of age, excluding sites that only administer flu vaccine). These data loggers should have a biosafe glycol-encased detachable temperature probe.

  - Even if digital data loggers are used, providers must still physically acknowledge the high/low temperatures at least twice daily.
- Temperature reports or logs must be maintained for a minimum of 3 years. It is recommended that sites meet this requirement by uploading the reports directly into the MIIS Temperature Log module.
- All providers must submit current temperature logs or reports with every vaccine order by uploading them into the MIIS.
- Providers that only receive influenza vaccine from MDPH must submit (via uploading to the MIIS) their temperature logs to the vaccine unit on a monthly basis starting in August and ending when they exhaust their supply of flu vaccine for the season.
- All vaccine stock must be rotated so vaccine with shortest shelf life is used first.
- All inventory must be checked at least monthly for short-dated (2-3 month shelf life) product that might not be used before expiring. This product must be transferred to another facility so that the vaccine is not wasted and restitution will not be necessary for your site by replacing the doses. Call the Vaccine Management Unit at 617-983-6828 if you need help facilitating this process. Providers must enter all vaccine transfer transactions into the MIIS Vaccine Management Module.

- Stabilize refrigerator temperatures by placing water bottles where vaccine should not be stored (in the door, on the bottom shelf of a refrigerator, or top shelf of a household-style refrigerator).
- Stabilize freezer temperatures by placing freezer packs in the door, on the floor and anywhere there is empty space.
- Store cold packs/gel packs in the refrigerator as part of your emergency preparedness, in case the need arises to transport vaccine during an emergency.
- Should the temperature of the vaccine storage unit need adjusting, it should only be done after vaccines have been removed and stored in a temporary storage unit. Please call the Vaccine Unit for consultation before attempting to do this.

B-3. Most state-supplied vaccines will be shipped directly to providers by a third party distributor. There may be times when some state-supplied vaccine might be transferred to another facility. In such circumstances, providers must transport vaccine in an insulated cooler with cold packs and a product temperature thermometer. Please consult with the Vaccine Management Unit for additional guidance on vaccine transport. Providers must enter all vaccine transfer transactions into the MIIS Vaccine Management Module.

B-4. The provider must maintain an accurate record of vaccines received from the MDPH Immunization Program. This record must include:

- Type of vaccine
- Manufacturer
- Lot number
- Expiration date
- Number of doses received

Please note: If your site is registered with the MIIS and have access to the Vaccine Management Module, this requirement is fulfilled.

B-5. Providers must accurately report to MDPH, through the MIIS Vaccine Management module, all required vaccine ordering and usage information, including a complete physical inventory and most recent temperature log when submitting vaccine orders. Temperature reports or logs should be uploaded to the MIIS Vaccine Management Module using the upload temp log function. All vaccine with the exception of varicella and MMRV vaccine will be shipped to you by McKesson Specialty Distribution. Varicella and MMRV vaccine will be shipped to you by Merck & Co., Inc.

B-6. Providers must complete a physical inventory of all state-supplied vaccines, including verification of expiration dates prior to submitting vaccine orders, and document this inventory electronically using the MIIS Vaccine Management Module.

- All expired, damaged or contaminated vaccine must be appropriately noted on an *Expired/Damaged Vaccine Return Request Form* and returned within 6 months of the expiration date. Those expired/damaged vaccines also need to be documented in the MIIS the next time a vaccine order is submitted.
- All expired or damaged vaccine must be removed from refrigerator units promptly and clearly labeled as “expired/damaged, do not use”.
- Mishandled or damaged vaccine must not be used.

- Determine vaccine ordering levels for each vaccine so that orders for all vaccines are placed at the same time. Orders cannot be placed more frequently than once per month. Depending on the quantity of vaccine the practice administers during the year, vaccine orders could be as frequent as every month, every 2-3 months or as needed. Expect order delivery no later than 14 days after order placement.
- Upon arrival, open box of vaccine immediately.
    - For shipments from McKesson, check the two transit temperature monitors. McKesson Specialty must be contacted at 877-836-7123 within 2 hours of receipt of vaccine if temperature monitors indicate a possible temperature variation.
    - For direct ship vaccines from Merck, check the shipment date located on the packing list and check the shipper insert supplied in the box. Shipments can be sent in a 2 day or 4 day box. Contact Merck Order Management Center at 800-637-8579 if date received is greater than the shipper insert indicates.
- Check to see if the packing list matches your vaccine order. If there are any problems or inconsistencies between your order and the vaccine received, contact the Vaccine Management Unit immediately at 617-983-6828.

B-7. Providers must agree to use state-supplied vaccines only within their own office/clinic setting. They must further agree not to sell or distribute vaccines provided by the MDPH Immunization Program to any other person, clinic or organization. Transferring of state-supplied vaccine may take place between enrolled MDPH providers but the transaction must be entered into the MIIS Vaccine Management Module.

B-8. Providers must maintain all records related to the VFC Program for a minimum of 3 years. These records must include the authorized representative's response about a child's eligibility, temperature logs and receipt of all state provided vaccines (see section B-2 and B-4). Release of such records will be bound by the privacy protection of Federal Medicaid law. If requested, the provider must make such records available to the MDPH Immunization Program or the Federal Department of Health and Human Services (DHHS).

B-9. The Primary Vaccine Coordinator and their back up, at each VFC provider site, must receive an educational training/contact annually. This training must cover all VFC requirements including proper storage and handling of state supplied vaccines. This requirement can be met by one of the following: VFC compliance site visit, webinar training or an in-person style presentation (e.g.; Immunization Update seminar, MIAP).

B-10. Providers must register for the Massachusetts Immunization Information System (MIIS) at www.contactMIIS.info in order to have access to the MIIS online Vaccine Management Module. The Vaccine Management Module includes provider enrollment, vaccine ordering and inventory management functionality. **Please Note: Online provider enrollment and vaccine ordering is now required for all pediatric (VFC**) sites. Contact the MIIS help desk at 617-983-4335 or MIISHELPDESK@STATE.MA.US with any questions regarding registration.

C. Billing and Charging for State-supplied Vaccine

C-1. Providers may not impose a charge for the cost of state-supplied vaccine to a patient or a third-party (e.g. insurance company or Medicaid).

C-2. Providers may charge an administration fee of not more than **$23.29** per dose for non-Medicaid (uninsured, underinsured or who are American Indian or Alaskan Native) VFC-eligible patients. For Medicaid VFC-eligible children, providers must accept the reimbursement for vaccine administration set by the Massachusetts Medicaid agency or the contracted Medicaid health plans. Providers may bill administration fees to third party payers in accordance with the terms of their contracts. Providers may not deny state-supplied vaccine to an established patient due to the inability of the child's parent/guardian/individual of record to pay the administration fee. "Established patient" applies only to private providers. FQHCs must administer state-supplied vaccine to any VFC-eligible child who presents for immunization services. MDPH recommends a sign that states, "NO ELIGIBLE CHILD MAY BE DENIED STATE-SUPPLIED VACCINE DUE TO INABILITY TO PAY ADMINISTRATION FEE" be posted in the provider's office. This sign is available from the MDPH Immunization Program in English and Spanish.

D. Vaccine Information Statements (VIS) and Consent

D-1. All providers, including public clinics and private offices, must provide a copy of the relevant and current edition of the Vaccine Information Statement (VIS) produced by the Centers for Disease Control and Prevention (CDC) before administering each dose of vaccine (NCVIA: 42 U.S.C. Section 300aa-26). Either a paper or electronic copy of the VIS must be available to read during the immunization visit. A paper copy must also be offered to the patients to take home. If they prefer to take home an electronic version, patients may be directed to CDC's patient download webpage: http://www.cdc.gov/vaccines/hcp/vis/current-vis.html to download the appropriate VIS onto their mobile device.

VISs provide risk-benefit information. VISs must be given for all vaccines and toxoids covered by the NCVIA, whether the vaccine was state-supplied or privately purchased. Each patient or parent/legal representative receiving vaccine must receive a copy of the VIS prior to administration of vaccine. There are additional requirements relating to the use of VISs in school-based or other programs, where the parent or legal representative is not likely to be present at the time of immunization. Please see item D4 below.

D-2. VISs must be used for the vaccines and toxoids specified in the NCVIA: measles, mumps and rubella containing vaccines (MMR); diphtheria and tetanus toxoids (DT); tetanus and diphtheria toxoids (Td); diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP); tetanus toxoids, diphtheria and acellular pertussis (Tdap); inactivated polio virus vaccine (IPV); hepatitis B vaccine (HBV); *Haemophilus influenzae* type B vaccine (Hib); varicella vaccine; pneumococcal conjugate 13-valent vaccine, hepatitis A vaccine (HAV); trivalent or quadrivalent influenza vaccine (both inactivated influenza vaccine [IIV] and live, attenuated influenza vaccine[LAIV]); rotavirus vaccine; meningococcal vaccines (MCV4 and MPSV4), varicella, serogroup B meningococcal (Men B) and human papillomavirus vaccine (HPV).

VISs should also be used for vaccines not currently specified in the NCVIA: hepatitis B immune globulin (HBIG); pneumococcal polysaccharide 23-valent vaccine; shingles vaccine

and other vaccines/toxoids. Information about the National Vaccine Injury Compensation Program can be found at http://www.hrsa.gov/vaccinecompensation.

D-3. All providers must maintain copies of the most up to date VISs in their office. All VISs are available in print and audio format in many languages. We recommend that someone in every provider office be assigned as the VIS coordinator. Copies of the most recent VISs (including translations in many foreign languages) are available online and can be downloaded from the Immunization Action Coalition website (www.immunize.org/vis). They are also available on the CDC website (http://www.cdc.gov/vaccines/hcp/vis/) and can be downloaded directly into a personal mobile device. Providers are encouraged to subscribe for email notification when a VIS is updated or a new VIS becomes available at the same website (http://www.cdc.gov/vaccines/hcp/vis/), click on "Get E-Mail Updates" and enter your e-mail address.

Appropriate materials and information may be substituted only if VISs are unavailable. This information should be culturally and linguistically appropriate and written at a reading level that can be easily understood. The National Childhood Vaccine Injury Act requires providers to supplement the VISs with "visual presentations" or "oral explanations" as needed. If patients are unable to read the VISs, it is up to the provider to ensure that they have access to the information they contain. VISs can be read to these patients or DVDs can be used as supplements. Audio files and versions of VISs that are compatible with screen reader devices are available on CDC's VIS website.

D-4. In school-based programs, or other programs where the parent or legal representative is not likely to be present at the time of immunization, the parent or legal representative may:

- Sign an individual consent form for the administration of each dose of vaccine, which includes acknowledging receipt of the VIS prior to each dose; or
- Sign a single consent form for the administration of an entire vaccine series (e.g. hepatitis B vaccine), if permissible by the institution's legal counsel. Single signature consent forms must:
    - Have a place for the parent/legal representative to acknowledge the receipt of the VIS and give permission for their child to be vaccinated with the complete series.
    - Describe the future process whereby the VIS shall be sent home prior to each subsequent dose.
    - State that a "*Withdrawal of Permission Form*" will be sent home with the VIS prior to each subsequent dose. This statement notifies the parent or legal representative that, based on their earlier permission, the next dose will be given on (list the date), unless the parent or legal representative signs the "*Withdrawal of Permission Form*."

In school-based programs, or other programs where the parent or legal representative is not likely to be present at the time of immunization, the provider must:

- Establish procedures for responding to questions from parent or legal representative by telephone or mail.
- Maintain, in the patient's medical record, the original consent signature(s), any "*Withdrawal of Permission Forms*" and dates the VISs were sent home to the parent or legal representative.

- Consult with the institution's legal counsel about any policies or requirements specific to the institution regarding consent and consent forms.

D-5. There is no federal or state requirement that providers, public or private, obtain the signature of patients, parents or legal representative acknowledging the receipt of the VIS. However, providers may choose to obtain these signatures.

Regardless of the setting or whether you are vaccinating children or adults, all providers are encouraged to consult with their legal counsel and/or follow their institution's policies regarding consent.

E. Documentation of Vaccine Administration

E-1. Providers must ensure that the permanent medical record (electronic or paper) of the recipient (or a permanent office log or file) contains all the required documentation for immunizations. This documentation shall consist of the following:

- Name and date of administration of the vaccine
- Vaccine manufacturer and lot number of the vaccine
- Name and title of person administering the vaccine
- Address of clinic where vaccine was given
- Edition date printed on the appropriate VIS, and
- Date the VIS was given to the vaccine recipient, or the parents/legal representative.

We also recommend that the vaccine type, dose, site and route of administration be documented. The initials of the vaccinator may be recorded in place of the full name and title, as long as the vaccine administration record contains a legend that has the full name and title and its corresponding initials.

Copies of vaccine administration records which can be used in your office are available by visiting http://www.mass.gov/dph/imm and selecting "Guidelines and Schedules."

E-2. Requirements for retention of written documentation vary and depend on licensing requirements:

- Clinics and hospitals: Must retain documentation for a period of *20 years* after the discharge or final treatment of the patient. State law includes a requirement for providers to notify MDPH before destroying records. (105 CMR: 140.302C, 105 CMR: 130.370A, MGL c111, s70).
- All other facilities (e.g., doctor offices, BOHs, VNAs, nursing homes, etc.): Must retain documentation for a period of *10 years* following the end of the calendar year in which the documentation occurred (NCVIA 1986).

State regulations regarding record retention and destruction (including new regulations pertaining to clinics/hospitals) can be found at Division of Health Care Facility Licensure and Certification website by visiting http://www.mass.gov/dph/dhcq, selecting "Regulations, Amendments and Public Hearings" and then selecting "Regulations."

An additional requirement applies to all categories of providers. If a notice of a claim or lawsuit has been made, the VIS, *Provider Enrollment Agreement* and other types of approved documentation pertaining to the matter must be retained until a final disposition of the claim or litigation (including appeals) has been made.

F. Vaccine Safety

F-1. Providers must report events as outlined in the *Vaccine Injury Table* (http://www.hrsa.gov/vaccinecompensation/vaccinetable.html). Also included as reportable are events listed in the vaccine manufacturer's package insert as contraindications to receiving additional doses of vaccine and any other serious or unusual event. Adverse events should be reported via the Vaccine Adverse Events Reporting System (VAERS). All providers except boards of health should obtain and forward the VAERS forms to:

VAERS
C/o ERC BioServices Corporation, a Division of Ogden Biomedical Service Group
First Street, Rockville, MD 20850

Board of health clinics and clinics run by visiting nurse associations (VNAs) for boards of health in Massachusetts should obtain and forward their VAERS forms to:

MDPH Immunization Program
State Laboratory Institute
305 South Street, Jamaica Plain, MA 02130
617-983-6800

VAERS forms and instructions are available in the FDA Drug Bulletin, the Physician's Desk Reference, or by calling VAERS at 1-800-822-7967. Providers can also report adverse events on line by utilizing the VAERS web site at http://www.vaers.hhs.gov.

F-2. Each vaccine recipient or the vaccine recipient's parent/legal representative must be furnished with a personal immunization record listing the type, dosage and the date (month, day, and year) of each vaccination. This can be generated from the MIIS or a provider's electronic health record (EHR) Information on the required immunization schedules, the vaccine injury compensation program and claim filing should also be made available.

F-3. The requirements contained in these guidelines must be communicated to any other health care personnel administering vaccine under the supervision of the physician signing this agreement.

F-4. In addition to reporting adverse events, MDPH also recommends reporting medication errors to the Institute for Safe Medication Practices (ISMP), a non-profit organization educating the healthcare community and consumers about safe medication practices.

Errors, near-errors or hazardous conditions to be reported include, but are not limited to, administering the wrong drug, strength, or dose of medications; confusion over look-alike drugs; incorrect route of administration; calculation or preparation errors; misuse of medical equipment; and errors in prescribing, transcribing, dispensing, and monitoring of medications. Providers can report medication errors by utilizing the ISMP website at: http://www.ismp.org.

G. Responsibilities of the Medical Director

G-1. The Medical Director, on behalf of himself or herself and all practitioners associated with the entity, is responsible for ensuring that state-supplied vaccine, including VFC vaccine, is administered in compliance with federal requirements for administration of vaccine. Failure to comply with federal requirements as outlined in this document

may constitute fraud and abuse, and may be punishable by law (Medicaid regulation: 42 CFR §455.15). The Medical Director must ensure that all communications from MDPH regarding immunizations or vaccine preventable diseases are disseminated to all relevant staff within his or her facility. MDPH recommends that each practice or agency have a communication plan and identify a person responsible for disseminating information.

G-2. Within the MIIS, the Medical Director is responsible for electronically signing the online *Provider Enrollment Agreement* and *Agreement to Comply with Federal and State Requirements for Vaccine Administration*, providing the MDPH Immunization Program with an accurate *Practice Profile* and providing the names of all physicians, physician assistants and nurse practitioners in the practice/clinic with their corresponding medical license number and Medicaid number where applicable.

G-3. MDPH Immunization Program staff are required to make an initial educational site visit to a provider who is enrolling in the VFC Program for the first time. The enrollment visit ensures that the provider and office staff are educated on the VFC Program requirements and have appropriate resources to implement these requirements.

G-4. The Medical Director understands and agrees that MDPH Immunization Program staff are required to make site visits every other year to evaluate vaccine handling and storage, VFC screening and record keeping, and to assess immunization levels. MDPH staff will also conduct unannounced visits to some providers to serve as "spot checks" for proper storage and handling practices.

G-5. The Medical Director is responsible for the staff who order, store, administer and report on vaccine usage. Any change in Medical Director must be reported to the MDPH Immunization Program within ten (10) days by calling the Vaccine Unit @ 617-983-6828.

G-6 The Medical Director is responsible for designating a Primary and Back-up Vaccine Coordinator. The Primary Vaccine Coordinator is responsible for oversight of all vaccine storage and handling including vaccine ordering and acting as vaccine shipping contact. They are also responsible for communicating vaccine policy, vaccine availability, updates and alerts to all pertinent staff. Any change in the Primary or Back-up Vaccine Coordinator must be reported to the MDPH Immunization Program within ten (10) days by calling the Vaccine Unit @ 617-983-6828.

G-7 The Medical Director is responsible for assuring that:

- Immunization policies and practices are in compliance with the *Standards for Child and Adolescent Immunization Practices* (Pediatrics October 2003;Vol.112, No.4, p.958-963) and
- The immunization schedule, dosage and contraindications followed are in compliance with those established by the Advisory Committee on Immunization Practices (ACIP).
- Supplying all ACIP-recommended vaccines except if the practice is designated as a "Specialty Provider" during the enrollment process. A "Specialty Provider" is defined as a provider that only serves (1) a defined population due to the practice specialty (e.g. OB/GYN, asthma/ allergy) or (2) a specific age group within the general population. "Specialty Providers" must indicate which vaccines are offered during enrollment.

Non-compliance with any of the above shall be cause to exclude the provider from continued participation in the MDPH Immunization Program/VFC Program.

H. Site Visits

H-1. Providers must be assessed for compliance with VFC and other federal requirements in accordance with MDPH guidelines every other year.

H-2. If any problems are identified with VFC compliance, the provider will receive follow-up contact and education, in accordance with CDC guidelines.

H-3. MDPH will perform some unannounced provider visits to check for proper storage and handling practices. Providers who have had prior storage and handling compliance issues may be prioritized for such visits.

I. Additional Guidance

Injection Safety for Patients and Health Care Personnel

(American Practitioners of Infection Control, World Health Organization, CDC)

I-1. Healthcare workers should follow the principles of injection safety. This includes the practice of one needle, one syringe, only one time; meaning using a needle and syringe only once, only on one patient.

In addition, hazards to healthcare workers must be minimized. By meeting the requirements of the OSHA Bloodborne Pathogen Standard and MDPH regulations, risk of needle stick injury is reduced. All needles used to attach to prefilled syringes or to use to administer vaccines should have built in sharps injury prevention features.

I-2. Providers should ensure that any used needles are disposed of immediately and appropriately in sharps containers that are rigid, puncture proof and can be closed, preventing needles from spilling out. The containers must contain the appropriate labels for biohazardous waste.

I-3. The person who prepares the vaccine for administration should be the same person who administers the vaccination. CDC strongly recommends providers draw vaccine only at the time of administration to ensure the cold chain is maintained and vaccine is not inappropriately exposed to light. Do not pre-draw vaccines before they are needed.

I-4. The federal Occupational Health and Safety Administration (OSHA) requires all employers to have an exposure control plan that delineates procedures for the management of needle stick injuries and other potential exposures to bloodborne pathogens.

I-5. **In the event of a needle stick injury or exposure to blood or body fluids:**

- Immediately wash the site of the needle stick injury with soap and water (flush splashes to nose, mouth or skin with water; irrigate eyes with clean water, saline or sterile irrigants).
- Immediately send the exposed individual to a medical provider to determine the hepatitis B vaccination status, including any post-vaccination screening that may have been done; testing for antibodies to hepatitis B, hepatitis C and HIV; and evaluation for the need for post-exposure prophylaxis.
- Immediately report the incident to your supervisor.
- See CDC emergency Needle Stick Information http://www.cdc.gov/niosh/topics/bbp/emergnedl.html.
- Questions about appropriate medical treatment for occupational exposures, 24 hour assistance is available from the clinicians' Post Exposure Prophylaxis Hotline (PEPline) at 1-888-448-4911. http://www.nccc.ucsf.edu.

Report vaccine administration errors to the Institute for Safe Medical Practices (ISMP) via the Medication Error Reporting Program (MERP) website: http://www.ismp.org. Review and implement protocols and staff training to minimize the possibility of further needle sticks.